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11	UNITED STATES I	DISTRICT COURT
12	FOR THE NORTHERN DIS	
14	SAN FRANCIS	CO DIVISION
15	CITY AND COUNTY OF SAN FRANCISCO, et al.,	Civil Case No.: 3:18-CV-07591-CRB
l6 l7	Plaintiffs,	DEFENDANTS' NOTICE OF JOINT MOTION AND JOINT MOTION TO DISMISS FIRST AMENDED
18	V.	COMPLAINT
19	PURDUE PHARMA L.P., et al.,	Date: June 19, 2020
20 21	Defendants.	Time: 10:00 a.m. Dept: Courtroom 6 Judge: Honorable Charles R. Breyer
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#### **NOTICE OF MOTION AND MOTION TO DISMISS**

#### TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on June 19, 2020, at 10:00 a.m., or as soon thereafter as available, in the courtroom of the Honorable Charles R. Breyer, located at 450 Golden Gate Avenue, Courtroom 6, 17th Floor, San Francisco, California 94102, undersigned Defendants will and hereby do move for an order dismissing with prejudice the claims of Plaintiffs City and County San Francisco and City Attorney Dennis J. Herrera ("City") asserted in the First Amended Complaint ("Compl." or "Complaint").

This Motion is based on this Notice of Motion and Motion, the Memorandum of Points and Authorities, the Manufacturer Defendants' Joint Request for Judicial Notice ("JRJN") and the accompanying Declaration of Charles C. Lifland and exhibits thereto, the pleadings and papers on file in this action, any other such matters of which the Court may take judicial notice, the arguments of counsel, and any other matter that the Court may properly consider.

#### MEMORANDUM OF POINTS AND AUTHORITIES

#### **INTRODUCTION**

The problem of opioid abuse is real, but lawsuits by local governments throughout the nation—including this suit by San Francisco and its City Attorney—are not a proper means of addressing this complex social problem. As Judge Alsup explained in dismissing a lawsuit brought by the City of Oakland seeking to hold a handful of energy companies liable for the impacts of global warming, certain "problem[s] deserve[] a solution on a more vast scale than can be supplied by a district judge or jury in a public nuisance case." *City of Oakland v. BP P.L.C.*, 325 F. Supp. 3d 1017, 1029 (N.D. Cal. 2018). And as the judge presiding over the State of Connecticut's consolidated opioid litigation explained:

The cities want ... money for the indirect harm they say the drug companies caused them.... But because they are suing in ordinary civil lawsuits their lawsuits cannot survive without proof that the people they are suing directly caused them the financial losses they seek to recoup. This puts the cities in the same position in claiming money as the brothers, sisters, friends, neighbors, and co-workers of addicts who say they have also suffered losses caused by the opioid crisis. That is to say—under long-established law—they have no claims at all.

City of New Haven v. Purdue Pharma, L.P., 2019 WL 423990, at \*1 (Conn. Super. Jan. 8, 2019). For the

reasons explained in the separate briefs of Manufacturers,<sup>1</sup> Distributors,<sup>2</sup> Walgreens Co. ("Walgreens")<sup>3</sup> and Anda, Inc., the City has not adequately alleged that it was harmed as a direct result of Defendants' alleged conduct. In addition to this fundamental defect, the City's claims should be dismissed for the reasons explained below.

#### I. SUMMARY OF ARGUMENT

RICO. In addition to the issues of proximate causation and the direct injury requirement—which are addressed in the separate briefs of the Manufacturers and the Distributors—the City fails to plead a valid RICO claim for multiple, independent reasons. First, the Complaint alleges as RICO injury increased municipal expenses, but under binding Ninth Circuit precedent those alleged injuries do not satisfy the RICO requirement of an injury to "business or property." *See Canyon County v. Syngenta Seeds, Inc.*, 519 F.3d 969, 976 (9th Cir. 2008). Second, the City's alleged injuries also fail to satisfy the "business or property" requirement because they are derivative of the personal injuries of City residents. Third, the Complaint fails to allege properly that each Defendant committed two or more predicate acts of "racketeering activity." Fourth, the City's conspiracy allegations fail because the City does not adequately plead a substantive violation of RICO; its vague and conclusory assertions of a conspiracy fall well short of what is required to plead an actionable RICO conspiracy; and the Complaint includes no well-pled

<sup>&</sup>lt;sup>1</sup> Defendants Cephalon Inc.; Teva Pharmaceuticals USA, Inc.; Allergan Finance, LLC (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.); Allergan Sales, LLC; Allergan USA, Inc.; and specially appearing Allergan plc.; Mallinckrodt LLC; SpecGx LLC; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Watson Laboratories, Inc.; Warner Chilcott Company LLC; Actavis South Atlantic LLC; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Actavis Totowa LLC; Actavis Kadian LLC; Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City; Actavis Laboratories FL, Inc. f/k/a Watson Laboratories, Inc.-Florida; Endo Pharmaceuticals Inc.; Endo Health Solutions Inc.; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc. f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc. f/k/a Janssen Pharmaceutica, Inc.; and Noramco, Inc. ("Noramco"). Noramco joins this Motion to the extent applicable and reserves all rights and defenses specific to it. Noramco is a manufacturer of active pharmaceutical ingredients only and does not (and did not at all material times relevant hereto) manufacture, package, brand, market, promote, distribute, or sell the finished drug products at issue in this litigation. Noramco thus is *at least* one step or more removed from the alleged conduct at issue and therefore, all claims against it should be dismissed as a matter of law.

<sup>&</sup>lt;sup>2</sup> Defendants AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation.

<sup>&</sup>lt;sup>3</sup> Because the only claim against Walgreens is public nuisance, Walgreens joins Sections II.A ("law of the case"), II.D (public nuisance), and II.E.1 and II.E.3 (federal preemption under the CSA).

allegations of an "illicit agreement" among Defendants.

UCL. The City's claim under California's Unfair Competition Law ("UCL") fails to the extent it is premised on Defendants' alleged failure to monitor and report suspicious orders to regulators. The City cannot state a claim under the UCL's "fraudulent" prong because the Complaint's allegations do not satisfy Fed. R. Civ. P. 9(b), see Kearns v. Ford Motor Co., 567 F.3d 1120, 1125 (9th Cir. 2009), and because members of the public cannot be deceived by Defendants' internal suspicious order monitoring systems or confidential reports to regulators, see Davis v. HSBC Bank Nev., N.A., 691 F.3d 1152, 1169 (9th Cir. 2012). Nor can the City state a claim under the UCL's "unlawful" prong, as no provision of state or federal law makes the failure to monitor or report suspicious orders substantively unlawful. See Samura v. Kaiser Found. Health Plan, Inc., 17 Cal. App. 4th 1284, 1301 (1993). Finally, the City cannot state a claim under the UCL's "unfair" prong because (i) Defendants' alleged conduct could not have caused harm to consumers as a matter of law, see Chang Bee Yang v. Sun Trust Mortg., Inc., 2011 WL 3875520, at \*8 (E.D. Cal. Aug. 31, 2011), as a consumer can obtain prescription opioids only if a doctor writes a prescription and a pharmacist exercises her independent judgment to fill it, and (ii) Defendants have a "strong justification" for manufacturing and distributing prescription opioids to pharmacies and hospitals, see Davis, 691 F.3d at 1170.

**Nuisance.** The City's statutory public nuisance claim fails as a matter of law for two reasons. First, the Complaint does not and cannot allege facts showing that any Defendant engaged in affirmative conduct with the requisite knowledge that its conduct would create a public health hazard. *See County of Santa Clara v. Atlantic Richfield Co.*, 137 Cal. App. 4th 292, 310 (2006). Second, the Complaint does not allege facts showing that Defendants' conduct caused the alleged nuisance. *See Melton v. Boustred*, 183 Cal. App. 4th 521, 542 (2010).

**Federal Preemption.** The City's claims also should be dismissed because they are preempted by federal law. First, the City's claims alleging Defendants failed to comply with the Controlled Substances Act ("CSA") and its implementing regulations are preempted because they conflict with the CSA's enforcement scheme, which grants the Drug Enforcement Administration ("DEA") broad authority and discretion to enforce the statute. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347–53 (2001). Second, the City's claims premised on Manufacturers' allegedly false marketing are preempted

because they conflict with the Federal Food, Drug, and Cosmetic Act ("FDCA"). *See Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 488–89 (2013). Finally, the City's claims premised on the erroneous assertion that the CSA requires registrants to refuse to ship suspicious orders are preempted because they disrupt the delicate regulatory balance Congress intended DEA to achieve in enforcing the CSA. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 874–86 (2000).

#### II. ARGUMENT

#### A. The MDL Court's Decisions in Different Cases Are Not "Law of the Case" Here.

The City's position that this Court should adopt the decisions of the MDL court in separate cases as "law of the case" here is incorrect. Like the decision of any other district court, an MDL court's decision in a different case is entitled to whatever weight its reasoning, treatment of precedent, and application of law to similar facts may command. But this Court remains free—indeed has a duty—to independently address the sufficiency of the allegations in the City's Complaint under Ninth Circuit and California law. As the Sixth Circuit recently explained when granting certain defendants' mandamus petition in the federal opioid MDL, "an MDL court's determination of the parties' rights in an individual case must be based on the same legal rules that apply in other cases, as applied to the record in that case alone." *In re Nat'l Prescription Opiate Litig.*, 2020 WL 1875174, at \*1 (6th Cir. Apr. 15, 2020).

The City's Complaint sets out five Counts: (i) RICO ("Marketing Enterprise"), (ii) RICO ("Supply Chain Enterprise"), (iii) California statutory public nuisance, (iv) California Unfair Competition Law claims, and (v) California False Advertising Law claims. The MDL court did not address the viability of any of these claims *in this case*; nor did it analyze these claims under the Ninth Circuit and California law that controls here.<sup>4</sup> The City's "law of the case" argument has no bearing on its claims under California law, and for four reasons, the MDL court's decision on a motion to dismiss the RICO claims of different plaintiffs in a different case does not bind the Court here.

<sup>&</sup>lt;sup>4</sup> The MDL court has addressed public nuisance claims, but never under California law. It also has considered versions of the preemption arguments set forth herein, but not under Ninth Circuit law.

First, the "law of the case" doctrine, which "generally preclude[s a court] from reconsidering an issue that has already been decided," applies only if the earlier ruling was "in the identical case." Thomas v. Bible, 983 F.2d 152, 154 (9th Cir. 1993); see Milgard Tempering, Inc. v. Selas Corp. of Am., 902 F.2d 703, 715 (9th Cir. 1990) (same).<sup>5</sup> The doctrine "do[es] not apply between separate actions." 18B Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 4478 (2nd ed. Apr. 2020 update) (hereinafter "Wright & Miller"); see also United States v. Maybusher, 735 F.2d 366, 370 (9th Cir. 1984) ("This matter is not entirely the same case ... [accordingly the] doctrine does not apply in this matter."). There is no exception for cases in an MDL. As the Sixth Circuit recently re-affirmed in the federal opioid MDL, "cases within an MDL 'retain their separate identities." In re Nat'l Prescription Opiate Litig., 2020 WL 1875174, at \*4 (quoting Gelboim v. Bank of Am. Corp., 574 U.S. 405, 413 (2015)); accord In re Korean Air Lines Co., 642 F.3d 685, 700 (9th Cir. 2011) ("individual cases that are consolidated or coordinated for pretrial purposes [in an MDL] remain fundamentally separate actions"). Because a ruling on an issue is law of the case only when "the *same* issue [is] presented a second time in the *same* case in the same court," GMAC Mortg., LLC v. McKeever, 651 F. App'x 332, 339 (6th Cir. 2016) (emphases in original), MDL rulings in one case are not binding law of the case in other MDL cases. See, e.g., In re Lipitor Antitrust Litig., 868 F.3d 231, 268 n.18 (3d Cir. 2017) (error to rely on decision in separate MDL as law of the case, a doctrine "that does not apply here because it only applies within a single litigation").

Second, an order is not law of the case unless it was necessary to a final judgment, and not merely an interlocutory order. See 58 Am. Jur. 2d New Trial § 415 (Feb. 2020 update); United States v. U.S. Smelting Ref. & Min. Co., 339 U.S. 186, 199 (1950); Peralta v. Dillard, 744 F.3d 1076, 1088 (9th Cir. 2014) (en banc) ("Pretrial rulings ... don't bind district judges for the remainder of the case."); see also Askins v. U.S. Dep't of Homeland Sec., 899 F.3d 1035, 1043 (9th Cir. 2018) (error for district court to invoke law of the case when it "did not enter a final judgment in the case"). The MDL court's decisions on defendants' motions to dismiss and for summary judgment were interlocutory rulings.

Third, Ninth Circuit precedent regarding RICO claims is materially different from the Sixth Circuit law purportedly applied by the MDL court. "The federal courts spread across the country owe respect to

<sup>&</sup>lt;sup>5</sup> Unless otherwise noted, all emphases are added and citations omitted.

each other's efforts and should strive to avoid conflicts, but each has an obligation to engage independently in reasoned analysis. Binding precedent for all is set only by the Supreme Court, and for the district courts within a circuit, only by the court of appeals for that circuit." *In re Korean Air Lines Disaster*, 829 F.2d 1171, 1176 (D.C. Cir. 1987) (Ginsburg, J.). As a corollary of this rule, any appeal from this Court's rulings regarding the City's RICO claims would necessarily be governed by Ninth Circuit precedent. *See*, *e.g.*, *Hill v. Henderson*, 195 F.3d 671, 677 (D.C. Cir. 1999) (in action transferred under 28 U.S.C. § 1404, court of appeals "would not be bound" by the decision of either transferor or transferee district court). It makes little sense to adopt as "law of the case" rulings entered by the MDL court based on Sixth Circuit precedent—especially where, as here, Ninth Circuit law is materially different in important respects. *See*, *e.g.*, *Peralta*, 744 F.3d at 1088 ("It makes no sense to say ... that if a district court realizes an earlier ruling was mistaken, it can't correct it, but must instead wait to be reversed on appeal.").

Finally, the law of the case doctrine is "discretionary," and a district court "properly exercises its discretion to reconsider an issue previously decided" where "the first decision was clearly erroneous." *Milgard Tempering*, 902 F.2d at 715. Even if the law of the case doctrine applied here in the first instance (and it does not), reconsideration of the MDL court's erroneous decisions would be warranted for the reasons explained herein and in Defendants' separate briefs, filed concurrently herewith.

#### B. The City's RICO Claims Should Be Dismissed.

The City fails to plead a valid RICO claim against Defendants<sup>7</sup> for multiple, independent reasons. First, the Complaint alleges increased municipal expenses as RICO injury, but under binding Ninth Circuit precedent those alleged injuries do not satisfy the RICO requirement of an injury to "business or property." *See* Part II.B.1. Second, the City's alleged injuries also fail to satisfy the "business or property"

<sup>&</sup>lt;sup>6</sup> As *Hill* recognizes, where an MDL court's rulings are subject to an immediate appeal pursuant to 28 U.S.C. § 1292(b) or Fed. R. Civ. P. 54(b), the court of appeal's "interlocutory decision is likely to be accepted as binding law of the case once the cases are transferred back to their courts of origin." 195 F.3d at 678. But the MDL court denied a request for certification for an immediate appeal. *See* MDL DE # 1283. Accordingly, the law of the Ninth Circuit would govern any appeal in this case.

<sup>&</sup>lt;sup>7</sup> The City's RICO claims addressed herein were asserted against the Purdue, Cephalon, Endo, Janssen, Mallinckrodt, Actavis, McKesson, Cardinal, Anda, and AmerisourceBergen entities. The City's "Opioid Supply Chain Enterprise" RICO claim, however, was not asserted against Janssen or Noramco. Compl. ¶ 797.

requirement because they are derivative of City residents' personal injuries. *See* Part II.B.2. Third, the Complaint fails to allege that each Defendant committed two or more predicate acts of "racketeering activity." *See* Part II.B.3. Finally, the City's conclusory conspiracy allegations cannot rescue its RICO claims. *See* Part II.B.4.

In addition to these fundamental defects, the Complaint fails adequately to allege proximate causation. Under RICO, a plaintiff must allege facts from which to infer a "direct relation between the injury asserted and the injurious conduct alleged." *Rezner v. Bayerische Hypo-Und Vereinsbank AG*, 630 F.3d 866, 837 (9th Cir. 2010). For the reasons explained in Manufacturers' and Distributors' separate motions to dismiss, the City fails to allege that it was injured as a *direct* result of Defendants' purported predicate acts.

## 1. The City Fails To Allege an Injury to Business or Property under Established Ninth Circuit Precedent Precluding Municipalities from Recovering for Governmental Expenditures.

The City does not allege a cognizable RICO injury. RICO is not applicable unless the alleged injury is to a plaintiff's "business or property." 18 U.S.C. § 1964(c). Under settled Ninth Circuit law, when "a governmental body acts in its sovereign or quasi-sovereign capacity, seeking to enforce the laws or promote the public wellbeing, it cannot claim to have been 'injured in [its] ... property' for RICO purposes." *Canyon County v. Syngenta Seeds, Inc.*, 519 F.3d 969, 976 (9th Cir. 2008). Thus, a "government cannot claim damages for general injury to the economy or 'to the Government's ability to carry out its functions." *Welborn v. Bank of New York Mellon Corp.*, 557 F. App'x 383, 387 (5th Cir. 2014) (quoting *Hawaii v. Standard Oil Co.*, 405 U.S. 251, 265 (1972)). In other words, a municipality's alleged injury must arise from "commercial activity," not "the provision of a public service." *Id.* 

The Ninth Circuit's decision in *Canyon County* controls here. In that case, a county brought a RICO claim against a defendant for allegedly engaging in an illegal scheme of hiring undocumented workers. 519 F.3d at 971. The county claimed that it incurred increased municipal expenditures as a result of the defendant's conduct and claimed as its RICO injury "additional monies ... expended on public health care and law enforcement services for [those] undocumented immigrants." *Id.* The Ninth Circuit rejected this claim, concluding "that the government does not possess a property interest in the law enforcement or health care services that it provides to the public; therefore, a governmental entity is not

'injured in its property' when greater demand causes it to provide additional public services of this type." *Id.* at 977. Otherwise, "any RICO predicate act that provoked any sort of governmental response would provide the government entity with standing to sue." *Id.* at 976.

Canyon County applies with full force here. The City's claimed RICO injuries are identical to those alleged in Canyon County—increased health care and law enforcement costs and losses. Compare 519 F.3d at 971, with Compl. ¶851(a) (alleging a "decrease in funding available for San Francisco's public services" because "[funding] was diverted to other public services designed to address the opioid epidemic"); see also id. ¶851(b)—(h) (alleging "increased costs" associated with: "health care and medical care"; "training emergency and/or first responders"; "providing police officers ... and other city employees with naloxone"; "emergency responses"; "mental health services"; maintaining "city property and public infrastructure" and "syringe disposal"; and "maintaining city and county jail system"); id. ¶882(a)—(h) (similar). These alleged injuries necessarily arise from the City's performance of governmental functions. As in Canyon County, the Complaint alleges that the City was forced to "spend[] money on the provision of additional public services" as a result of Defendants' alleged misconduct. 519 F.3d at 976; accord Compl. ¶¶851, 882. Accordingly, the City, "may not claim th[os]e costs as damages to its property for purposes of civil RICO standing." Canyon County, 519 F.3d at 979.

The MDL court "declined to follow" the Ninth Circuit's *Canyon County* decision, asserting that "the Sixth Circuit [has not] adopted the holding" and that recovery by the Ohio plaintiffs was therefore possible under the "broadest reading of Sixth Circuit precedent." *In re Nat'l Prescription Opiate Litig.*, 2018 WL 6628898, at \*9–10 (N.D. Ohio Dec. 19, 2018). This Court, however, is bound by the Ninth Circuit's holding in *Canyon County. See supra* Part II.A.

The MDL court's efforts to narrow *Canyon County*, in dicta, are unpersuasive. The MDL court quoted the Ninth Circuit's statement that a local government may not recover "based *solely* on the fact that it has spent money in order to act governmentally" as "impl[ying]" that public services expenditures *are* recoverable so long as something more is alleged, such as the "scope and magnitude of the opioid crisis" having led a political subdivision to dedicate more of its resources than "what a government might ordinarily be expected to." *In re Nat'l Prescription Opiate Litig.*, 2018 WL 6628898, at \*10 (emphasis in original). But there is no "greater-expenditures-beyond-the-norm" exception to *Canyon County*'s reading

of RICO's statutory "business or property" limitation. And the MDL court's attempt to inject its own policy views by seizing on the word "solely" is directly undermined by the Ninth Circuit's unequivocal holding "that the government does not possess a property interest in the law enforcement or health care services that it provides to the public" and, therefore, "is not 'injured in its property' when greater demand causes it to provide additional public services of this type." *Canyon County*, 519 F.3d at 977.

Nor can the City evade *Canyon County* by asserting that it provided health care and other public services by incurring antecedent costs such as purchasing naloxone to address opioid-related overdoses by members of the public. *See* Compl. ¶¶ 851(d), 881(d); *see also id.* ¶ 61 (purchase of naloxone was a public expenditure to make it available as a public service to "members of the public"). Any attempt to recover such costs ignores the key distinction "between the status of a governmental entity acting to enforce the laws or promote the general welfare and that of a governmental entity acting as a consumer or other type of market participant." *Canyon County*, 519 F.3d at 976. Just as the costs of providing law enforcement services were not recoverable under *Canyon County* even though the government entity there had to purchase weapons and cars used by the police department, the costs of providing medical services to residents are not recoverable by the City here even if it had to purchase medicine or supplies to provide those services. *See id.* ("[a]II government actions require the expenditure of money").

## 2. The City's Alleged Injury Is Derivative of Personal Injury, and Thus Not an Injury to Business or Property.

"The terms 'business or property' are ... words of limitation which preclude recovery for personal injuries and the pecuniary losses incurred therefrom." *Doe v. Roe*, 958 F.2d 763, 767 (7th. Cir. 1992); *see also, e.g., Diaz v. Gates*, 420 F.3d 897, 898 (9th Cir. 2005) ("We agree with the Seventh Circuit [in *Doe*]."). Accordingly, "RICO's private cause of action is limited to particular kinds of injury—excluding, for example, personal injuries." *Bokaie v. Green Earth Coffee LLC*, 2018 WL 6813212, at \*5 (N.D. Cal. Dec. 27, 2018) (quoting *RJR Nabisco, Inc. v. European Cmty.*, 136 S. Ct. 2090, 2108 (2016)).

Here, the City's claimed damages arise from the alleged personal injuries of its residents. But for those citizens' use or misuse of opioids, the City alleges it would not have incurred the medical and other expenses that constitute its claimed injuries. *See, e.g.*, Compl. ¶ 882; *see also id.* ¶ 883 ("But for the opioid-addiction epidemic created by the RICO Supply Chain Defendants' conduct, San Francisco would

not have lost money or property."). Because such damages "flow from" personal injuries, they are not injuries to the City's "business or property" for purposes of RICO. See Jackson v. Sedgwick Claims Management Services, Inc., 731 F.3d 556, 565–66 (6th Cir. 2013) (en banc) ("[B]oth personal injuries and pecuniary losses flowing from those personal injuries fail to confer relief under [RICO]."); Haw. Health & Welfare Tr. Fund for Operating Eng'rs v. Philip Morris, Inc., 52 F. Supp. 2d 1196, 1200 (D. Haw. 1999) (increased costs to third-party payors arising out of beneficiaries' tobacco use was not an injury to "business or property" because "the injury is, in all material respects, personal injury to the smokers").

The MDL court sought to distinguish these cases, holding that RICO bars only "pecuniary losses [that] arise *directly* out of a personal injury." *In re Nat'l Prescription Opiate Litig.*, 2018 WL 6628898, at \*7. That distinction, however, finds no support in any Ninth Circuit authority. Moreover, to the extent that the City's alleged injury flows only indirectly from the use or abuse of opioids by its residents, the City fails to plead a direct connection between its alleged injury and Defendants' predicate acts. *See, e.g.*, *Holloway v. Clackamas River Water*, 739 F. App'x 868, 869 (9th Cir. 2018) (affirming dismissal of RICO claims where alleged injuries "either do[] not constitute a harm to a specific business or property interest or lack[] the requisite [causal] connection to alleged racketeering activity").

#### 3. The City Fails To Allege Racketeering Activity.

The City's RICO claims should also be dismissed because the Complaint fails adequately to allege that each Defendant committed two or more predicate acts of "racketeering activity." 18 U.S.C. § 1961.

Mail and Wire Fraud. The principal RICO predicate acts alleged in the Complaint are mail and wire fraud, Compl. ¶¶ 860, 865, and under well-established law, "predicate acts of mail and wire fraud [must be pled] with sufficient particularity." *Chagby v. Target Corp.*, 358 F. App'x 805, 808 (9th Cir. 2009) (citing Fed. R. Civ. P. 9(b)); *accord Washington v. Lowe's HIW Inc.*, 75 F. Supp. 3d 1240, 1252 (N.D. Cal. 2014) (Breyer, J.) ("Federal Rule of Civil Procedure 9(b) requires that fraud claims, including

<sup>&</sup>lt;sup>8</sup> The distinction is also irrelevant because, as even the MDL court admitted, "perhaps" the "provision of medical treatment and emergency response services[] arise *directly* out of the personal injury of the citizens." *In re Nat'l Prescription Opiate Litig.*, 2018 WL 6628898, at \*9. At a minimum, the Court should hold here that the City's RICO claims are barred insofar as they seek to recoup the costs of medical expenses incurred in treating its residents.

civil RICO fraud, be pleaded with specificity...."). Because the Complaint does not satisfy this requirement, the mail and wire fraud allegations fail.

To plead RICO predicate acts of mail or wire fraud with sufficient particularity, a plaintiff must specify the "time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentations." *Swartz v. KPMG LLP*, 476 F.3d 756, 764 (9th Cir. 2007); *see also Sanford v. MemberWorks, Inc.*, 625 F.3d 550, 558 (9th Cir. 2010) (same); *Washington*, 75 F. Supp. 3d at 1252 (same). Here, for the reasons explained in Manufacturers' and Distributors' separate briefs, the Complaint fails adequately to plead predicate acts of mail or wire fraud as to any member of either group.

Controlled Substances Act Violations. Under the federal CSA, it is unlawful for a registrant "to furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under ... subchapter [I] or subchapter II" of the CSA. 21 U.S.C. § 843(a)(4). The City alleges that Defendants' purported failure to report suspicious orders violated Section 843(a)(4), and that those failures constitute "racketeering activity" under RICO. *See* Compl. ¶¶ 862–64.9 That argument is doubly wrong.

First, violations of Section 843(a)(4) do not constitute RICO predicate acts. RICO's enumerated predicate acts include the "felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance." 18 U.S.C. § 1961(1)(D). But violations of Section 843(a)(4) do not fall within that language because they consist only of "furnish[ing]" false information in, or "omit[ting]" material information from, certain "report[s]" or "record[s]"—not "buying, selling, or otherwise dealing" in controlled substances, 21 U.S.C. § 843(a)(4). While a magistrate judge's report and recommendation in the MDL suggested that furnishing false information or omitting material information in reports to DEA constitutes "concealment," *In re Nat'l Prescription Opiate Litig.*, 2018 WL 4895856,

<sup>&</sup>lt;sup>9</sup> Although the Complaint refers to "violations" of 21 U.S.C. § 823 by Distributors (not Manufacturers) as predicate acts, *see* Compl. ¶ 865(c), this appears to be a typographical error. Section 843 prohibits "knowingly or intentionally furnishing false or fraudulent information in, and/or omitting material information from, documents filed with the DEA." Section 823 contains only registration procedures for manufacturers and distributors, not felonious prohibitions on the conduct of such entities. *See* 28 U.S.C. § 823; *see also infra* Part II.C.2 (discussing unlawful prong of the UCL).

at \*21 (N.D. Ohio Oct. 5, 2018), report and recommendation adopted in relevant part, 2018 WL 6628898 (N.D. Ohio Dec. 19, 2018), the felonious "concealment" that is actionable under Section 1961(1)(D) plainly has to do with the controlled substances themselves, not recordkeeping. See United States v. Veal, 23 F.3d 985, 988 (6th Cir. 1994) (holding that ultimate fate of controlled substances, i.e., whether they were diverted to illegal use, has no bearing on Section 843(a)(4) "recordkeeping charges"). 11

Second, Defendants' alleged failure to report suspicious orders did not violate any requirement imposed by subchapter I or subchapter II of the CSA. While the CSA requires registrants to furnish various records and reports to DEA, *see* 21 U.S.C. § 827 ("Records and reports of registrants"), it did *not* (at any time prior to October 2018) require registrants to report "suspicious orders." Indeed, subchapters I and II of the CSA did not even use the term "suspicious orders" until October 2018. Because suspicious order reports were not required to be "made, kept or filed" under the CSA, any alleged failure to make such reports to DEA plainly did not violate 21 U.S.C. § 843(a)(4).

#### 4. The City Fails To Allege a Conspiracy.

The City has not specifically pled a conspiracy claim under Section 1962(d). Indeed, Section 1962(d) is only mentioned in one paragraph in the Complaint. See Compl. ¶ 828. Nor is there a separate

<sup>&</sup>lt;sup>10</sup> The magistrate judge also asserted that Defendants' interpretation of Section 843 would render "the entirety of § 1961(1)(D) a nullity." MDL DE # 1025 at 46. But that is patently incorrect: drug dealers routinely "conceal[]" drugs, and *that* conduct would constitute a predicate act under Defendants' interpretation of Section 1961(1)(D).

<sup>&</sup>lt;sup>11</sup> Any doubt about this conclusion is resolved by the rule of lenity, which "requires courts to limit the reach of criminal statutes to the clear import of their text and construe any ambiguity against the government." *United States v. Millis*, 621 F.3d 914, 916–17 (9th Cir. 2010). At best for the City, it is ambiguous whether Section 843(a)(4)'s prohibition on furnishing or omitting certain information in reports or records qualifies as "the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance."

This reality is underscored by the fact that Congress, for the first time in October 2018, amended the CSA to require registrants to notify DEA "upon discovering a suspicious order." See Pub. L. No. 115-271, 132 Stat. 3894, 3956 (Oct. 24, 2018) (codified at 21 U.S.C. § 832). Had the statute already contained requirements relating to suspicious order reporting, Congress would not have needed to amend the statute in 2018. See Ross v. Blake, 136 S. Ct. 1850, 1858 (2016) ("When Congress amends legislation, courts must 'presume it intends [the change] to have real and substantial effect.""); see also Pierce County v. Guillen, 537 U.S. 129, 145 (2003) (rejecting interpretation of statute that would have rendered the amendment an "exercise in futility"). Further, the suspicious order provision added in October 2018 does not establish "felonious" conduct as to registrants. See 21 U.S.C. §§ 842(c)(1)(B)(ii), 842(c)(2)(D).

Count addressing any conspiracy claim. That is insufficient. *See Monterey Bay Military Hous., LLC v. Ambac Assurance Corp.*, 2018 WL 3439372, at \*13 (N.D. Cal. July 17, 2018) (requiring plaintiffs to "separate [any] claims asserted under §§ 1962(c) and (d)"). Nonetheless, to the extent the Court finds that the City pled such a claim, it fails for numerous reasons.

First, the City "cannot claim that a conspiracy to violate RICO existed if they do not adequately plead a substantive violation of RICO." *De Los Angeles Gomez v. Bank of Am., N.A.*, 642 F. App'x 670, 675 (9th Cir. 2016); *see also, e.g., Religious Tech. Ctr. v. Wollersheim*, 971 F.2d 364, 367 (9th Cir. 1992) ("Because we find that RTC has failed to allege the requisite substantive elements of RICO, the conspiracy cause of action cannot stand."). Here, because the City has not pled a substantive RICO violation, *see supra* Part II.B.1–3, its RICO conspiracy claim fails.

Second, the vague and conclusory allegations of a conspiracy among "Defendants," Compl. ¶ 547, fall well short of what is required to plead an actionable RICO conspiracy. RICO conspiracy claims based upon mail fraud and wire fraud must be pled with particularity under Fed. R. Civ. P. 9(b). *See Edwards v. Marin Park, Inc.*, 356 F.3d 1058, 1066 (9th Cir. 2004). But "Rule 9(b) does not allow a complaint to merely lump multiple defendants together." *Swartz*, 476 F.3d at 764 (plaintiff "failed to sufficiently detail the roles played by the defendants in the alleged conspiracy"). Indeed, "[e]ven Rule 8(a) pleading requires plaintiffs to identify the specific defendant charged with committing a particular predicate act, rather than collectivizing a group of defendants." *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Young*, 1994 WL 88129, at \*15 (S.D.N.Y. Mar. 15, 1994); *see also Lak v. California Dep't of Child Support Servs.*, 2017 WL 6541922, at \*10 (C.D. Cal. Dec. 21, 2017) (dismissing RICO claim under Rule 8; "absent *specific* allegations identifying what actions *each* defendant took against Plaintiff and how such action violated Plaintiff's rights, the [complaint] fails to provide Defendants with fair notice" (emphases in original)). Yet lumping Defendants together is all the Complaint does here: the City's conspiracy allegations (Compl. ¶¶ 697–717) do not plead any specific conduct by any specific Defendant.

Third, the Complaint includes no well-pled allegations of an "illicit agreement" on the part of Defendants to commit predicate acts—an essential element of RICO conspiracy. *See, e.g., De Los Angeles*, 642 F. App'x at 675; *Couch v. Cate*, 379 F. App'x 560, 567 (9th Cir. 2010); *Am. Dental Ass'n v. Cigna Corp.*, 605 F.3d 1283, 1295 (11th Cir. 2010). The Ninth Circuit has repeatedly instructed that a

claim based on conspiracy must plead *facts* that plausibly suggest a genuine conspiracy, as opposed to mere parallel conduct. *See Kendall v. Visa U.S.A., Inc.*, 518 F.3d 1042, 1049 (9th Cir. 2008) (it is insufficient for a plaintiff to allege that the defendant "knowingly, intentionally and actively participated in an individual capacity in the alleged scheme," as "[a]llegations of facts that could just as easily suggest rational, legal business behavior by the defendants as they could suggest an illegal conspiracy are insufficient"). For example, in *In re Musical Instruments & Equip Antitrust Litigation*, 798 F.3d 1186, 1193 (9th Cir. 2015), the Ninth Circuit explained that allegations of parallel conduct among industry members are insufficient to plausibly plead a conspiracy; instead, a conspiracy claim must plead "something more," "some further factual enhancement," a "further circumstance pointing toward a meeting of the minds" of the alleged co-conspirators. *Id.* at 1193 (quoting *Bell Atlantic Corp. v. Twombly*, 500 U.S. 544, 557 (2007)). These principles apply with full force to a RICO conspiracy claim. *See Mazur v. eBay Inc.*, 2008 WL 2951351, at \*5 (N.D. Cal. July 25, 2008) (alleging the mere existence of common motivation to make money does not sufficiently plead a RICO conspiracy claim).

Here, there are no allegations of any improper agreement. The Complaint instead relies upon vague and conclusory assertions that Manufacturers "agreed among themselves" to establish a fraudulent "marketing network," Compl. ¶ 697, and that all Defendants agreed to "increas[e] the supply of opioids," *id.* ¶ 711, without any details about when this occurred, who was involved, or what specific agreements were reached. These conclusory assertions fail as a matter of controlling law because "a conclusory allegation of agreement at some unidentified point does not supply facts adequate to show illegality." *Twombly*, 550 U.S. at 557.

At most, the City alleges that some of the Manufacturers sponsored some of the same medical professionals, organizations, and publications and referenced the same article in marketing materials about prescription opioid medications. *See*, *e.g.*, Compl. ¶¶ 328, 344, 403–79, 495–502, 709. The Complaint does not include any such allegations as to Distributors or Walgreens. Even as to Manufacturers, these allegations at best show "parallel conduct that could just as well be independent action," not an unlawful conspiracy. *Twombly*, 550 U.S. at 556–57. That is particularly true here, given that Manufacturers are competitors. As the Ninth Circuit has made clear, "interdependent firms may engage in consciously parallel conduct through observation of their competitors' decisions, even absent an agreement," and

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allegations that Manufacturers adopted "similar policies across an industry ... does not reveal anything more than similar reaction to similar pressures within an interdependent market, or conscious parallelism." *In re Musical Instruments & Equip. Antitrust Litig.*, 798 F.3d at 1196.

Likewise, the City alleges that Defendants participated in the same trade associations (the Pain Care Forum and HDA), which had committees, held conferences about opioid sales, and published guidelines about preventing opioid diversion. *See* Compl. ¶¶ 609–24. Under controlling Ninth Circuit law, "mere participation in trade-organization meetings where information is exchanged and strategies are advocated does not suggest an illegal agreement." *In re Musical Instruments & Equip. Antitrust Litig.*, 798 F.3d at 1196; *see also In re Citric Acid Litig.*, 191 F.3d 1090, 1098 (9th Cir. 1999) ("[T]rade associations often serve legitimate functions, such as providing information to industry members, conducting research to further the goals of the industry, and promoting demand for products and services."). The allegations about the Pain Care Forum and HDA are entirely consistent with lawful industry conduct.<sup>13</sup> The City's Section 1962(d) conspiracy claim thus fails.<sup>14</sup>

#### C. The City's Unfair Competition Law Claim Should Be Dismissed.

The Complaint alleges two separate theories under the UCL, both of which fail as a matter of law.<sup>15</sup>

First, the Complaint alleges that Manufacturers "circulated false and misleading information concerning, among other things, the safety and efficacy of ... opioids ... and falsely and misleadingly downplayed or omitted the risk of addiction arising from their use." Compl. ¶ 911. This theory, which does not implicate the non-Manufacturer Defendants, is addressed in Manufacturers' separate motion to dismiss.

<sup>&</sup>lt;sup>13</sup> The Complaint's passing references to "aid[ing] and abett[ing]" liability, Compl. ¶¶ 838, 861, also do not help the City, as "[s]uch a theory of [civil] liability is not available under RICO." *In re Chrysler-Dodge-Jeep Ecodiesel Mktg. Litig.*, 295 F. Supp. 3d 927, 984 (N.D. Cal. 2018).

<sup>&</sup>lt;sup>14</sup> The MDL court did not address RICO conspiracy at the motion to dismiss stage and the opinion's analysis of the conspiracy allegations was done under Ohio law, did not address Rule 9(b), and was otherwise cursory and flawed. *See In re Nat'l Prescription Opiate Litig.*, 2018 WL 6628898, at \*10–11 (adopting R&R with regard to civil conspiracy under Ohio law). Ninth Circuit precedent dictates a different result here.

<sup>&</sup>lt;sup>15</sup> The City does not assert a claim under the UCL against Walgreens.

Second, the Complaint alleges that all Defendants (except Walgreens) "unlawfully violated" controlled substances law and "engaged in fraudulent and unfair practices by failing to design and operate a system to monitor suspicious orders of controlled substances, and fail[ing] to disclose such suspicious orders" to regulators. Compl. ¶912. For the reasons explained below, this theory fails to state a claim under the UCL because the City does not adequately allege facts showing that Defendants acted fraudulently, unlawfully, or unfairly.

#### 1. The City Cannot State a Claim under the Fraudulent Prong of the UCL.

The City's allegation that Defendants "engaged in fraudulent ... practices by failing to design and operate a system to monitor suspicious orders of controlled substances, and fail[ing] to disclose such suspicious orders," Compl. ¶ 912, does not state a claim.

As a threshold matter, the City fails to allege a violation of the UCL's fraudulent prong with the requisite particularity. "Claims stated under the fraud[ulent] prong of the UCL are subject to the particularity requirements of [Rule] 9(b)." *In re Anthem, Inc. Data Breach Litig.*, 162 F. Supp. 3d 953, 990 (N.D. Cal. 2016) (citing *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009)). The City's Complaint merely alleges in generic terms that Defendants failed to monitor and report suspicious orders. Because the City does not identify any specific "suspicious orders" that any particular Defendant should have reported, the City's allegations under the UCL's fraudulent prong should be dismissed. *See Holmes v. Johnson & Johnson*, 617 F. App'x 639, 644 (9th Cir. 2015) (affirming dismissal under the UCL's fraudulent prong because plaintiff's "allegations were insufficiently specific under Rule 9(b)").

Even beyond this threshold bar, the City's allegations fail on their own terms. "A business practice is fraudulent under the UCL if members of the public are likely to be deceived." *Davis v. HSBC Bank Nev., N.A.*, 691 F.3d 1152, 1169 (9th Cir. 2012). Members of the public are not likely to be—indeed cannot be—deceived by Defendants' alleged failure to maintain internal suspicious order monitoring systems or to provide confidential reports to regulators. For this fundamental reason, the City's claim under the UCL's fraud prong fails as a matter of law. *See, e.g., Express, LLC v. Fetish Group, Inc.*, 464 F. Supp. 2d 965, 980 (C.D. Cal. 2006) (rejecting UCL claim under fraudulent prong where plaintiff "d[id] not point to any evidence suggesting the representations ... were disseminated to the public, let alone likely to deceive the public").

#### 2. The City Cannot State a Claim under the Unlawful Prong of the UCL.

Nor can the City state a claim under the UCL's unlawful prong. The UCL's "unlawful" prong "borrows violations of other laws." *Cel-Tech Commc'ns, Inc. v. L.A. Cellular Tel. Co.*, 20 Cal. 4th 163, 180 (1999). Unlawful practices under the UCL are "limit[ed] ... to acts which are made unlawful by the [underlying statute]." *NorthBay Healthcare Grp. - Hosp. Div. v. Blue Shield of Ca. Life & Health Ins.*, 342 F. Supp. 3d 980, 987 (N.D. Cal. 2018). Accordingly, to state an unlawful practices claim, an underlying statute must "declare [the relevant practice] to be unlawful *as a matter of substantive law.*" *Samura v. Kaiser Found. Health Plan, Inc.*, 17 Cal. App. 4th 1284, 1302 (1993); *see also Davis*, 691 F.3d at1168 ("To be 'unlawful' under the UCL, the [practice] must violate another borrowed law."); *Shroyer v. New Cingular Wireless Servs., Inc.*, 622 F.3d 1035, 1044 (9th Cir. 2010) (noting that to establish "a violation of the 'unlawful' prong," a plaintiff must "allege that [defendant] engaged in a business practice forbidden by law"). "[R]egulatory guidelines and requirements" that "do not define unlawful acts ... cannot [be the] predicate [of] a cause of action" under the UCL. *Samura*, 17 Cal. App. 4th at 1301.

Here, the Complaint fails to allege an unlawful act or practice. The City alleges that Defendants failed to monitor and report suspicious orders "as required of 'registrant[s]' by the federal CSA, 21 C.F.R. § 1301.74(b)." Compl. ¶ 912; see also id. ¶ 913 (alleging that certain Defendants failed to meet requirements of "Cal. Bus. & Prof. Code § 4169.1"). But the CSA regulatory provisions merely set out procedures relating to the registration of manufacturers and wholesale distributors; no provision of state or federal law makes the failure to monitor or report suspicious orders substantively unlawful.

On the federal level, to manufacture or distribute a Schedule I or II controlled substance lawfully, a manufacturer or wholesale distributor must apply for a registration with DEA and renew that registration annually. 21 U.S.C. § 822(a)(1); 21 C.F.R. § 1301.11; 28 C.F.R. § 0.100(b). Congress directed that DEA "shall register an applicant" unless it determines "that the issuance of such registration is inconsistent with the public interest." 21 U.S.C. § 823(a)–(b). "In determining the public interest" for purposes of registration, the statute instructs DEA to consider various factors, including the applicant's "maintenance of effective controls against diversion." *Id.* § 823(a).

DEA has promulgated regulations addressing "effective controls" in Part 1301—a part whose "[s]cope" is limited (consistent with 21 U.S.C. § 823's focus on registration) to the "[p]rocedures

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governing the *registration*" of manufacturers, distributors, and other registrants. 21 C.F.R. § 1301.01. The regulation states that registrants "shall provide effective controls and procedures to guard against theft and diversion of controlled substances" and then in the next sentence specifies the meaning of "effective controls": "to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72–1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion." § 1301.71(a). The regulations further provide that "[s]ubstantial compliance with the standards set forth in §§ 1301.72–1301.76 may be deemed sufficient" by the agency "after evaluation of the overall security system." 21 C.F.R. § 1301.71(b).<sup>16</sup>

Sections 1301.72 to 1301.76 largely address the physical handling of controlled substances. They set forth a long series of "security requirements," including, for example, specifications for storage areas, cabinets, vaults, cages, alarms, compounding areas, and the like. See, e.g., 21 C.F.R. § 1301.72. Only one such provision—21 C.F.R. § 1301.74(b)—addresses suspicious orders. It indicates that, as part of the overall security requirements in the effective controls provisions, registrants shall (i) "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and (ii) "inform" DEA "of suspicious orders when discovered." 21 C.F.R. § 1301.74(b).<sup>17</sup>

This registration framework does not impose a substantive legal "duty," violation of which would trigger automatic legal liability on Defendants here. Rather, as the foregoing discussion demonstrates, the security requirements set forth in Sections 1301.72 to 1301.76 are simply factors to be considered as part of DEA's overall assessment of a registrant for purposes of determining whether the registrant is in

<sup>&</sup>lt;sup>16</sup> Before DEA may permanently suspend or revoke a registration, an individualized proceeding before the federal agency is required, including an order to show cause, a hearing, an opportunity "to submit a corrective action plan on or before the date of appearance," and judicial review. 21 U.S.C. § 824(c).

<sup>&</sup>lt;sup>17</sup> The regulations define "suspicious orders" as "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b). California law incorporates substantially the same definition. Cal. Bus. & Prof. Code § 4169.1.

The California provisions on which the City relies are equally unavailing. Cal. Bus. & Prof. Code § 4169.1—which did not become effective until January 1, 2018<sup>19</sup>—merely incorporates the terms of the federal regulations, stating that wholesalers "shall notify the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler by providing the board a copy of the information that the wholesaler provides to [DEA]." That provision does not declare any practice to be unlawful. Indeed, a separate provision of the same Article—a provision that conspicuously omits any reference to "suspicious orders"—defines prohibited activities and violations. *See* Cal. Bus. & Prof. Code § 4169(a) ("A person or entity shall not do any of the following: ..."). It is well established that when a statute or regulation explicitly lists members of a class (here, prohibited acts), it "impliedly excludes" other items that are not listed. *See Silvers v. Sony Pictures Ent., Inc.*, 402 F.3d 881, 885 (9th Cir. 2005) ("The doctrine of *expressio unius est exclusio alterius* as applied to statutory interpretation creates a presumption that when a statute designates certain persons, things, or manners of operation, all omissions should be understood as exclusions.").<sup>20</sup>

<sup>&</sup>lt;sup>18</sup> The MDL court's advisory opinion regarding the CSA, *see* MDL DE # 2483, does not compel a contrary conclusion. The MDL court addressed an abstract argument without anchoring it to any analysis of the elements of any claim—and certainly not any claim under the California UCL. In any event, the decision was based on a truncated and fundamentally incorrect interpretation of the CSA and its implementing regulations. Those provisions do not, as the MDL court opined, impose various "duties" on registrants but rather, as explained *supra*, identify factors for DEA to consider in determining whether to issue, suspend, or revoke a federal registration. As such, the CSA and its regulations do not, as required to state a UCL claim, "declare [failure to report suspicious orders] to be unlawful *as a matter of substantive law*." *Samura*, 17 Cal. App. 4th at 1301.

<sup>&</sup>lt;sup>19</sup> The Complaint contains no well-pled allegation that any Defendant failed to report suspicious orders at any time *after* that provision's effective date of January 1, 2018. Nor does the Complaint allege that they failed to provide the Board of Pharmacy with "a copy of the information" that Defendants submitted to DEA, which is all that the statute requires. Cal. Bus. & Prof. Code § 4169.1. For these additional reasons, the City's reliance on Section 4169.1 is unavailing.

<sup>&</sup>lt;sup>20</sup> The Complaint also references in passing provisions of California law requiring wholesalers to report to the Board of Pharmacy "all sales of dangerous drugs subject to abuse as designated by the Board for reporting, in excess of amounts to be determined by the Board from time to time ... within thirty (30) days of the request in the form specified by the Board." Cal. Code Regs. tit. 16, § 1782; *see also* Cal. Bus. &

Because the state and federal regulatory regimes on which the City relies do "not define unlawful acts," the regulatory provisions cited in the Complaint "cannot [be the] predicate [of] a cause of action under section 17200." *Samura*, 17 Cal. App. 4th at 1302; *see Elec. Indus. Serv. Bureau, Inc. v. Phila. Indem. Co.*, 2018 WL 7286502, at \*4 (N.D. Cal. July 11, 2018) (concluding unlawful practices claim could not be premised on provision that "specifies" when "the liability of a surety accrues ... rather than [provides] a basis for liability if violated"); *Martinez v. Welk Group, Inc.*, 907 F. Supp. 2d 1123, 1139 (S.D. Cal. 2012) ("[B]ecause [the underlying statute] only defines 'deceit,' and does not provide an applicable violation, such provision cannot be the basis of Plaintiff's claim.").

Samura is instructive. There, the plaintiff's UCL claim was premised on defendants' alleged violations of provisions of California's Knox-Keene Act "set[ting] forth certain requirements for health care service plans" and "regulat[ing] the content of the disclosure form provided to prospective members." 17 Cal. App. 4th at 1301. Explaining that the provisions relied on by the plaintiff "pertain to the exercise of the Department of Corporation's regulatory power" and do not set forth independently "unlawful act[s]," the court reversed the trial court and held that the alleged violation of those provisions could not give rise to a claim under the UCL:

It is immaterial whether or not the challenged ... business practices comply with ... the Knox-Keene Act because the statutes do not define unlawful acts that may be enjoined under Business and Professions Code section 17200. In basing its order on these provisions, the trial court assumed a regulatory power over [the defendant] that the Legislature has entrusted exclusively to the Department of Corporations .... To the extent that the order on appeal is based on portions of the Knox-Keene Act having a purely regulatory import, it improperly invades the powers that the Legislature entrusted to the Department of Corporations.

Prof. Code § 4164(a) ("A wholesaler or third-party logistics provider licensed by the board that distributes controlled substances, dangerous drugs, or dangerous devices within or into this state shall report to the board all distributions of dangerous drugs and controlled substances that are subject to abuse, *as determined by the board*."). The Complaint, however, fails to allege that any Defendant failed to comply with any request by the Board for any such reporting. And for Manufacturers, the state law cited in the Complaint is largely inapplicable as a matter of law: by its terms, Cal. Bus. & Prof. Code § 4164(a) applies only to "[a] wholesaler or third-party logistics provider licensed by the board," neither of which are defined to include Manufacturers. *See id.* §§ 4043. 4045. The same is true for Cal. Bus. & Prof. Code § 4301, which California courts have applied only to pharmacies. *See, e.g., Hoang v. Cal. State Bd. of Pharmacy*, 230 Cal. App. 4th 448, 527 (2014) (applying § 4301 to pharmacist and noting board "is authorized to bring formal disciplinary proceedings against anyone holding a pharmacy license").

Id. at 1300–02. Likewise here, the statutes and regulations on which the City relies "pertain to the exercise of [DEA's and the Board of Pharmacy's] regulatory power." Id. at 1300. Because there is "nothing in the [se] statute [s] or related regulations that declares [failure to monitor suspicious orders] to be unlawful as a matter of substantive law," the City "cannot predicate a cause of action under section 17200 on violation" of the CSA's implementing regulations or Cal. Bus. & Prof. Code § 4169.1. Id. at 1302.

#### 3. The City Cannot State a Claim under the Unfair Prong of the UCL.

The City likewise fails to state a claim for relief under the unfair prong of the UCL. While the definition of "unfair" "is currently in flux," the Ninth Circuit has "endorsed" a balancing test. *Lozano v*. *AT & T Wireless Servs.*, *Inc.*, 504 F.3d 718, 735–36 (9th. Cir. 2007). Pursuant to that test, the "harm to the consumer" is "balanc[ed]" "against the utility of the defendant's practice." *Id.* at 735. The City's allegation that Defendants "oversuppl[ied] ... opioids to San Franciscans by ... failing to make reasonable efforts to prevent diversion," Compl. ¶ 915, does not satisfy this test.

First, the Complaint fails to allege that Defendants caused harm to California consumers. Manufacturers do not sell pharmaceutical products directly to consumers. Distributors likewise are wholesalers that sell pharmaceutical products to retail pharmacies, *not* "consumers" within the meaning of the UCL. *See* Compl. ¶ 33 (distributors "act as middlemen between drug companies and pharmacies"). Unless and until doctors write prescriptions, patients present those prescriptions to pharmacists, and pharmacists fill those prescriptions, the products that wholesalers deliver from manufacturers to pharmacies (and other dispensaries) would never reach consumers and can cause no harm. Thus, Defendants' alleged failure to identify and report suspicious orders could not have caused substantial harm to consumers as a matter of law. *See Chang Bee Yang v. Sun Trust Mortg., Inc.*, 2011 WL 3875520, at \*8 (E.D. Cal. Aug. 31, 2011) (concluding plaintiffs failed to state a claim where they did "not sufficiently allege[] why they suffered any harm *as a result* of the" alleged unfair practice).

Second, the City's allegations do not posit any plausible theory under which Defendants' alleged failure to report suspicious orders *could* have caused harm to consumers. A consumer can lawfully access a prescription opioid medication only if it is prescribed by a doctor. If anything, the reductions in supply available to pharmacies that the City suggests might have followed from enhanced reporting would have made it *more* difficult for consumers to fill such legitimate prescriptions.

Third, Defendants have a "strong justification" for manufacturing and facilitating the distribution of opioid medications to pharmacies and hospitals. *See Davis*, 691 F.3d at 1170. Regulated medications—including prescription opioids—"have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people," 21 U.S.C. § 801(1); *see also infra* n.23. Defendants' manufacture and shipment of FDA-approved medications to state-licensed and DEA-registered dispensaries thus has significant utility.

#### D. The City's Nuisance Claim Should Be Dismissed.

The City seeks to hold Defendants liable for opioid abuse under a public nuisance theory, describing the alleged nuisance as the "ongoing, significant, unlawful, and unreasonable interference with the public health, welfare, safety, peace, comfort, and convenience of the San Francisco community" allegedly caused by Defendants' marketing practices, suspicious-order monitoring systems, and/or dispensing practices. Compl. ¶ 892, 893–94, 899. The Court should dismiss this claim for at least two reasons: the City does not and cannot allege facts showing (i) that any Defendant engaged in affirmative conduct with the requisite knowledge of the public health hazard the conduct allegedly created, or (ii) that Defendants' conduct caused the alleged nuisance.

#### 1. The City Cannot Allege Affirmative Conduct with Knowledge of the Hazard.

Under California law, a public nuisance claim cannot succeed based on the "mere manufacture and distribution of [the product] or the[] failure to warn of its hazards." *County of Santa Clara v. Atl. Richfield Co.*, 137 Cal. App. 4th 292, 310 (2006). Rather, to state a claim, a plaintiff must allege something *in addition* to manufacturing and distributing the product and failing to warn of its hazards. A defendant must also "take affirmative steps" and act "with knowledge of the public health hazard that this [conduct] would create." *Id.* at 309–10. Put differently, a plaintiff must allege either that defendants *intended* to create the nuisance for which the plaintiff seeks to recover, or knew that it would result. And constructive knowledge—i.e., what a defendant "should have known"—is insufficient; to the contrary, a plaintiff must allege that a defendant had "actual knowledge" that its conduct would create a "public health hazard." *People v. ConAgra Grocery Prods. Co.*, 17 Cal. App. 5th 51, 83 93 (2017). As a matter of law, the City does not and cannot satisfy this requirement.

The Complaint pleads no facts to support its conclusory assertions about Defendants' supposed intent or knowledge of potential health hazards. Indeed, the core conduct at issue is Manufacturers' marketing, all Defendants' distribution, and Walgreens pharmacists' dispensing of prescription opioid medications that have been approved as safe and effective by the FDA, *e.g.*, Compl. ¶ 23, yet the alleged nuisance goes far beyond that core conduct, and includes "widespread effects" ranging from illicit drug use within San Francisco to the City's increased expenses in addressing improperly disposed needles, more "frequent 911 callers," and increased smuggling of narcotics into correctional facilities, *id.* ¶¶ 55–57. At most, the allegations suggest Defendants' knowledge of the known risks of prescription opioid medications generally. They do not support a reasonable inference that Defendants took any "affirmative steps" with knowledge that such conduct would result in the opioid abuse crisis that constitutes the claimed public nuisance.<sup>21</sup>

## 2. The City Fails To Plead Facts Sufficient To Establish That Defendants' Conduct Caused the Alleged Nuisance.

California law requires a plaintiff in a public nuisance action to plead and prove causation—both causation in fact and proximate causation. *Melton v. Boustred*, 183 Cal. App. 4th 521, 542 (2010) ("The elements of a cause of action for public nuisance include ... causation."). To establish causation in fact, a plaintiff must plead and prove that the "conduct was a substantial factor in causing" the nuisance. *Gregory Vill. Partners, L.P. v. Chevron U.S.A., Inc.*, 805 F. Supp. 2d 888, 901 (N.D. Cal. 2001). Conduct does not meet this standard if the alleged harm still would have occurred in its absence, unless the conduct would have been sufficient to bring about the harm. *See Rutherford v. Owens-Illinois, Inc.*, 16 Cal. 4th 953, 958–59 (1997). A plaintiff does not establish proximate causation if the alleged harm was the "result of the independent intervening acts of others." *Martinez v. Pac. Bell*, 225 Cal. App. 3d 1557, 1566 (1990) (dismissing public nuisance claim where "a separate and intervening act" caused the harm).

<sup>&</sup>lt;sup>21</sup> The public nuisance claim also fails as a matter of law under Cal. Civ. Code § 3482 to the extent it seeks to hold Defendants liable for engaging in lawful activity, including marketing and distributing opioid products approved for long-term treatment of chronic pain as safe and effective for that indication. Like the UCL, California's public nuisance statute contains a safe harbor provision barring liability for conduct permitted by another provision of law. *See* Cal. Civ. Code § 3482 ("Nothing which is done or maintained under the express authority of a statute can be deemed a nuisance.").

Here, the Complaint alleges in conclusory fashion that "[t]he unlawful conduct of each of the Defendants was a substantial factor in producing [the] harm" that the City seeks to abate. Compl. ¶ 903. As explained in the parties' separate industry group and individual motions, the City falls far short of pleading the requisite facts plausibly to allege causation.

#### E. Federal Law Preempts the City's State-Law Claims.

In addition to their substantive defects, the City's claims are preempted by federal law. Insofar as the City alleges that Defendants violated purported "duties" to report or refuse to ship "suspicious orders" of—or, in the case of Walgreens, to refuse to fill prescriptions for—opioid medications, such claims are preempted by the federal CSA. Insofar as the City alleges that Manufacturers misrepresented the risks and benefits of opioid medications, that claim is preempted by the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.* ("FDCA").

## 1. Buckman Preempts the City's Claims Premised on Defendants' Purported Failures To Comply with the CSA and its Implementing Regulations.

The City's claim that Defendants failed to comply with the federal CSA and its implementing regulations is preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), and its progeny.<sup>22</sup>

In *Buckman*, the plaintiffs alleged personal injuries from a medical device for which the defendant, a consulting company, had helped the manufacturer obtain FDA approval. *Id.* at 343. Plaintiffs asserted state law claims based on the company's failure to report information to the FDA during the approval process: had the company reported the information, they claimed, the FDA would not have approved the medical device, and they would not have been injured by it. *Id.* But the Supreme Court held that federal law preempted such claims because they "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350.

The Supreme Court explained that in this reporting context, there is no presumption against preemption: "Policing fraud against federal agencies is hardly a field which the States have traditionally

<sup>&</sup>lt;sup>22</sup> The City may argue that its claims arise in part under California law. California law, however, did not contain any provisions addressing suspicious order reporting until January 1, 2018. *See supra* n.19. Accordingly, no state-law claim could possibly be premised on alleged state-law reporting failures that occurred prior to that date.

occupied." *Id.* at 347. "To the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* 

Plaintiffs' state law claims conflicted with federal law because "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and ... this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Id.* at 348. Because "[t]he FDA ... ha[d] at its disposal a variety of enforcement options" and "[t]his flexibility [wa]s a critical component of the statutory and regulatory framework under which the FDA pursue[d] difficult (and often competing) objectives," the Supreme Court concluded that the plaintiffs' state law claims were preempted. *Id.* at 350, 352.

Subsequent Ninth Circuit decisions make clear that a comprehensive federal enforcement scheme impliedly preempts state law claims where, as here, federal law is a critical aspect of those claims—and particularly when the plaintiff alleges fraud on a federal agency. *See, e.g., Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1206 (9th Cir. 2002). The Ninth Circuit has emphasized

the potential problems inherent in allowing a state court (or a federal court interpreting state law) to ascertain the propriety of disclosures made by an applicant to a federal agency in response to the mandates of federal legislation. In particular, we are troubled that an applicant's disclosures under [federal law], although not challenged by ... the very agency empowered by Congress to enforce [the federal law at issue], may be judged illegal under state law.

*Id.* at 1207. Thus, *Buckman* preemption applies to state law claims premised on a defendant's alleged misrepresentations or omissions to a federal agency with "substantial enforcement powers" where "the existence of the [underlying federal statutory] requirements are ... a critical element of [plaintiff]'s state-law case." *Id.* at 1206.

Under *Buckman*, the City's claims against Defendants are preempted to the extent they are premised on alleged failures to comply with the federal CSA and its implementing regulations. The City alleges that Defendants "failed to report suspicious sales, as required by ... federal law." Compl. ¶ 33. But Congress created a comprehensive enforcement scheme that vests DEA with authority to enforce the CSA—including the regulatory provisions relating to identifying and informing DEA about "suspicious

orders." Congress, moreover, granted DEA discretion in exercising this enforcement authority because that federal agency has the expertise to balance the CSA's competing aims of "foster[ing] the beneficial use of those medications" and "prevent[ing] their misuse."<sup>23</sup>

Just as the *Buckman* plaintiffs claimed that, had the defendant fully reported testing data to FDA, the agency would not have approved the device and users would not have been injured, so too the City claims that, had Defendants reported suspicious orders to DEA, DEA would have investigated and shut down "bad" pharmacies and doctors such that addiction would have been prevented or curbed and the City would have spent less on addiction-related services. Also as in *Buckman*, the City's claim of non-reporting would require a court to assess whether Defendants had complied with federal regulations and, in so doing, to interfere with the "delicate balance of statutory objectives" that guides DEA in enforcing its regulations. *See* 531 U.S. at 348.

Recognizing the disruption such lawsuits would cause, this Court recently concluded that municipalities' state-law claims were impliedly preempted by the Clean Air Act. As this Court explained, "[n]ot only is EPA better positioned than the Counties to regulate [the conduct at issue], but if the Counties were permitted to regulate this conduct, the size of the potential ... penalties could significantly interfere with Congress' regulatory scheme." *In re Volkswagen "Clean Diesel" Marketing, Sales Practices, & Prods. Liability Litig.*, 310 F. Supp. 3d 1030, 1044–45 (N.D. Cal. 2018) (Breyer, J.). Thus, as this Court concluded, when a plaintiff "seek[s] to impose additional, significant sanctions for the same conduct" that Congress has provided penalties for—and especially when "other counties and states bring similar claims"—"the potential penalties could dwarf those [under the federal scheme], which would seriously undermine the congressional calibration of force." *Id.* at 1045; *see also Amgen Inc. v. Sandoz Inc.*, 877

<sup>&</sup>lt;sup>23</sup> Gonzalez v. Raich, 545 U.S. 1, 24 (2005). Congress enacted the CSA "to control the supply and demand of controlled substances," *id.* at 19, which requires a regulatory balance. If the distribution of drugs is too restricted, the American people will be deprived of essential medicines "necessary to maintain [their] health and general welfare." 21 U.S.C. § 801(1). If the distribution of drugs is too free, their improper use will have a "detrimental effect on the health and general welfare." 21 U.S.C. § 801(2). Congress vested DEA with authority to promulgate regulations (through notice-and-comment rulemaking) and enforce the statute with *both* those competing considerations in mind.

F.3d 1315, 1329 (Fed. Cir. 2017) (concluding conflict preemption barred plaintiff's UCL claim because "compliance with the [federal statute's] detailed regulatory scheme in the shadow of 50 States' tort regimes, and unfair competition standards, could dramatically increase the burdens on [regulated parties] beyond those contemplated by Congress in enacting the [statute]").<sup>24</sup>

Likewise here, DEA is better positioned than cities and counties throughout the nation to enforce the federal CSA. Permitting such private plaintiffs to seek substantial penalties based on purported violations of the CSA would undermine the delicate balance that Congress struck in enacting the statute. Accordingly, the City's claims are preempted under *Buckman*.

## 2. The City's Marketing-Based State-Law Claims Are Also Preempted under *Buckman*.

Federal preemption principles, including those applied in *Buckman*, likewise foreclose the City's marketing-based claims against Manufacturers. The Supreme Court has made clear that claims seeking to impose a duty to alter FDA-approved labeling or otherwise to market FDA-approved prescription medications in a way that conflicts with federal law are subject to implied preemption under the FDCA. *Mut. Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 488–89 (2013). This is true regardless of whether the claims challenge FDA-approved labeling or instead challenge marketing materials that are consistent with FDA-approved labeling. *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 394 (6th Cir. 2013) (citing *Kordel v. United States*, 335 U.S. 345, 349–50 (1948) and 21 C.F.R. §§ 202.1, 202.100). The public record makes clear that FDA approved numerous opioid medications for long-term treatment of chronic pain, including all of the extended-release long-acting ("ER/LA") opioids marketed by the Manufacturers.<sup>25</sup> In doing so, FDA found "substantial evidence" that those opioids are sufficiently safe and effective for use, under supervision of a licensed physician, in accordance with—and despite the

<sup>&</sup>lt;sup>24</sup> Insofar as plaintiffs sought to enforce the federal CSA, the MDL court never substantively engaged with the argument that plaintiffs' claims were preempted. Instead, the MDL court summarily cited the "reasons previously articulated" for its rejection of a different *Buckman* argument. *See* MDL DE # 2565 at 9, 22, # 1499 at 43, # 1025 at 50–52. Because the MDL court never seriously grappled with the argument that *Buckman* preempts claims to enforce the CSA's suspicious order reporting provisions, its summary rejection of the argument on inapposite grounds is not entitled to any deference by this Court.

<sup>&</sup>lt;sup>25</sup> Duragesic, Kadian, Nucynta ER, Opana ER, and Exalgo—ER/LA opioids of different potencies—are all specifically approved for long-term treatment of chronic pain.

known risks described in—their FDA-approved labeling. *See* 21 U.S.C. § 355(d); 21 C.F.R. § 314.50. After making that determination, FDA has subsequently (i) denied, in 2013, a petition to exclude long-term use for chronic non-cancer pain from opioids' approved indication and to impose dosage and duration limits, JRJN Ex. 9, and (ii) issued a May 2019 memorandum that—again—rejected the notion that opioids are generally unsafe for chronic pain, finding that these medications "provide clinically significant analgesic benefit, including for pain for which other analgesics are inadequate," JRJN Ex. 11.

Contrary to these determinations by FDA, the City's marketing-based claims, at their core, seek to hold Defendants liable for statements consistent with Defendants' allegedly "false position that opioids were safe and effective for treatment of chronic pain." Compl. ¶ 453. But courts have repeatedly held that state law claims are preempted where, as here, they would either (i) require a prescription drug manufacturer to make statements about safety or efficacy that differ from what FDA required, see, e.g., Cerveny v. Aventis, Inc., 855 F.3d 1091, 1105 (10th Cir. 2017) (finding state-law tort claim preempted where FDA previously denied citizen petition to change product's labeling to include at-issue warning); In re Celexa & Lexapro Mktg. & Sales Practices Litig., 779 F.3d 34, 42–43 (1st Cir. 2015) (finding FAL, CLRA and UCL claims preempted where FDA found drug effective after considering information plaintiff alleged was deceptively omitted from label); Utts v. Bristol-Meyers Squibb Co., 251 F. Supp. 3d 644, 663–73 (S.D.N.Y. 2017), or (ii) hold a manufacturer liable for promoting a prescription drug as safe and effective for its FDA-approved indications, see Prohias v. Pfizer, Inc., 490 F. Supp. 2d 1228, 1234 (S.D. Fla. 2007) (claims were preempted because they "conflict[ed] with the FDA's jurisdiction over drug labeling, and specifically its approval of [certain indications]"). This Court should do the same. 27

<sup>&</sup>lt;sup>26</sup> To the extent the City challenges alleged "off-label" promotion, *see*, *e.g.*, Compl. ¶¶ 466, 737, federal preemption applies nonetheless. As the Supreme Court explained in *Buckman*, the FDCA provides the FDA with exclusive authority and "a variety of enforcement options" to address alleged off-label promotion by "regulat[ing] in this area without directly interfering with the practice of medicine." 531 U.S. at 347–50. Given that "[t]he FDCA does not provide a private right of action" to enforce its provisions, the FDA's exclusive authority with respect to off-label promotion preempts state law claims based thereon. *Perdue v. Wyeth Pharms., Inc.*, 209 F. Supp. 3d 847, 851–52 (E.D.N.C. 2016).

<sup>&</sup>lt;sup>27</sup> This Court should not adopt the MDL court's motion to dismiss ruling on preemption of claims involving opioid marketing. There, the court found "the state law claims [we]re not premised upon inappropriate labeling" because the Ohio plaintiffs "dispute[d] that their claims [we]re based on

## 3. The City's Claims Premised on the Alleged Duty To Halt Suspicious Orders Are Also Preempted.

The City's claims are further preempted to the extent they are premised on its erroneous assertion that the CSA requires registrants to refuse to ship certain orders placed by licensed pharmacies and other registrants—or, the case of Walgreens, to override the professional judgment and dispensing decisions of licensed pharmacists. *See, e.g.*, Compl. ¶¶ 579, 585, 893–94. State law is preempted when it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona v. United States*, 567 U.S. 387, 399 (2012). Because the City's claims disrupt the delicate regulatory balance Congress intended DEA to achieve in enforcing the CSA, they stand as such an obstacle.

Geier v. American Honda Motor Co., 529 U.S. 861 (2000), is instructive. There, plaintiffs attempted to impose liability on a car manufacturer for failing to include airbags. In plaintiffs' view, "the more airbags, and the sooner, the better." *Id.* at 874. But this approach differed from that of the Department of Transportation, which preferred "a mix of different devices introduced gradually over time" that would "lower costs, overcome technical safety problems, encourage technological development, and win widespread consumer acceptance." *Id.* at 874–75. Accordingly, the Supreme Court concluded that the plaintiffs' claims conflicted with the objectives of the regulatory scheme and were preempted by federal law. The City's liability theory—premised on the view that "the [fewer opioids], and the sooner, the better," *see id.* at 874—is likewise inconsistent with DEA's obligation under the CSA "to ensure that there is no interference with the dispensing of controlled substances to the American public in accordance with the sound medical judgment of their physicians." Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,719–20 (DEA Sept. 6, 2006); *see also supra* n.23.

allegations that Defendants *falsely* claimed their medications were 'safe and effective for the long-term treatment of chronic non-cancer pain." MDL DE # 1025 at 49–50. The City's allegations, however, make clear that its state-law marketing-based claims in fact *are* "premised upon inappropriate labeling," specifically, Manufacturers' allegedly "*false* position that opioids were safe and effective for treatment of chronic pain." Compl. ¶ 453.

 $^{28}$  In fact, there is no obligation under the federal CSA or its implementing regulations to refuse to ship a "suspicious order." *See*, *e.g.*, MDL DE # 2159 at 7–14.

The City may argue that it seeks to employ state law to impose penalties only for actions that it claims are prohibited by federal regulation.<sup>28</sup> However, imposing a greater remedy than DEA imposes still creates a conflict: "[I]t does not follow that the state and federal authorities may supplement each other.... The conflict lies in remedies, not rights.... [W]hen two separate remedies are brought to bear on the same activity, a conflict is imminent." *Garner v. Teamsters, Chauffeurs & Helpers Local Union No.* 776 (A.F.L.), 346 U.S. 485, 498–99 (1953). Thus, where (as here) a state law claim seeks to impose additional liability on defendants for their alleged non-compliance with federal regulations, the claim is preempted.

In short, imposition of state tort liability would prevent DEA from fulfilling its mandate—regulating under and enforcing the CSA—to strike the balance between policing diversion and ensuring that Americans have access to necessary medicines. Because the City's claims would interfere with accomplishment of the purposes and objectives of Congress in enacting the CSA, the claims are preempted.

#### III. CONCLUSION

For the foregoing reasons, the City's claims should be dismissed with prejudice.

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I, Sonya Winner, hereby attest, pursuant to N.D. Cal. Civil L.R. 5-1, that the concurrence to the filing of this document has been obtained from each signatory hereto.

DATED: April 17, 2020 By: /s/ Sonya D. Winner

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